

**EXHIBIT A, Gregory T. Bales, M.D.**

Murphy, Michellyn	<del>2:12-cv-02600</del>
Soltanshshi, Victoria	2:12-cv-02688
Mattingly, Deborah	2:12-cv-03097

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC.  
PELVIC REPAIR SYSTEMS  
PRODUCT LIABILITY LITIGATION

MDL No. 2327

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THIS DOCUMENT RELATES TO:

Cases Identified in the Motion

**MEMORANDUM OPINION AND ORDER**  
**(*Daubert* Motion re: Gregory T. Bales, M.D.)**

Pending before the court is the Motion to Exclude the General Opinion Testimony of Gregory T. Bales, M.D. [ECF No. 2054] filed by the plaintiffs. The Motion is now ripe for consideration because briefing is complete.

**I. Background**

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively “Ethicon”), among others.

In this MDL, the court’s tasks include “resolv[ing] pretrial issues in a timely and expeditious manner” and “resolv[ing] important evidentiary disputes.” Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

*Litigation in Products Liability Cases* 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order (“PTO”) No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.<sup>1</sup>

## II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties’ misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert*’s core considerations for assessing expert

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<sup>1</sup> The plaintiffs identified the Wave 1 cases affected by this Motion in their attached Exhibit A [ECF No. 2054-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert

testimony may be evaluated at trial. At trial, the expert testimony will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of “junk science” looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court’s prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

### **III. Legal Standard**

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these

standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

- (1) whether a theory or technique can be or has been tested;
- (2) whether it has been subjected to peer review and publication;
- (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and
- (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

*Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts “principles and methodology” above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g., Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

#### **IV. Discussion**

Dr. Bales is a board-certified urologist who has performed over 1,000 pelvic floor surgeries, placed over 1,000 midurethral slings, and treated mesh complications.

**a. Properties**

The plaintiffs seek exclusion of Dr. Bales's testimony about whether or not clinical data and evidence indicate that mesh degrades, is cytotoxic, is biocompatible, or causes an inflammatory response. They argue Dr. Bales is unqualified to offer this testimony because he lacks training in chemical engineering, structural engineering, or biomechanics. The lack of engineering expertise does not render Dr. Bales unqualified to offer these opinions, particularly because he intends to opine only on the clinical aspects of these characteristics. Dr. Bales has performed thousands of pelvic mesh procedures and treated patients experiencing complications. Resp. 9. This extensive clinical experience, combined with his review of peer-reviewed literature, qualifies Dr. Bale to opine on mesh's reaction to and effect on the human body. The plaintiffs' Motion on this matter is **DENIED**.

**b. Complications**

The plaintiffs challenge the reliability of Dr. Bales's complication rate opinions relating to native tissue procedures based on their allegation that Dr. Bales failed to cite to certain studies that calculated much lower complication rates. The plaintiffs point out that one study Dr. Bales relies on—the Weber Study—was later updated in 2011 to account for altered definitions of “prolapse” and “success,” but Dr. Bales did not rely on the updated study. Finally, the plaintiffs state that Dr. Bales's complication rate opinions should be excluded because they are “not supported by overwhelming current scientific literature.” Mem. Supp. Mot. re: Dr. Bales 7 [ECF

No. 2057].

Dr. Bales's opinions are supported by peer-reviewed scientific literature, and Dr. Bales testified that he considered the updated 2011 Weber Study and explained why he did not rely on it. To the extent that the plaintiffs believe that Dr. Bales did not adequately consider conflicting studies, the plaintiffs are free to cross-examine Dr. Bales on those points. The standards elucidated in *Daubert* do not require Dr. Bales to offer opinions that are "supported by overwhelming current scientific literature." Mem. Supp. Mot. re: Dr. Bales 7. Dr. Bales's opinions are passably reliable under *Daubert*. The plaintiffs' Motion is **DENIED** regarding Dr. Bales's native tissue procedure complication rate opinions.

The plaintiffs next argue that Dr. Bales should be precluded from opining that dyspareunia is not a significant risk of POP surgeries using mesh because such opinions are not supported by the scientific literature. Dr. Bales, however, does not offer this opinion in his report. Instead, Dr. Bales states that "[d]yspareunia is a long-standing, well-known complication that is well established in the surgical literature regarding the surgical repair of POP." Bales Report 8 [ECF No. 2054-2]. Dr. Bales concludes by saying that "[o]verall, the studies comparing Prolift to native tissues repairs do not show any statistically significant differences in rates of de novo dyspareunia, pelvic pain or sexual dysfunction." *Id.* Thus, Dr. Bales makes no opinion regarding "significant risk." Instead, Dr. Bales discusses "significant differences in rates," and he backs up his opinions with citations to scientific literature. To the extent that the plaintiffs believe that Dr. Bales failed to consider contrary scientific



literature, they may cross-examine him on those points. The plaintiffs' Motion is **DENIED** regarding Dr. Bales's dyspareunia opinions.

The plaintiffs next challenge Dr. Bales's opinions regarding the clinical significance of mesh contracture. The plaintiffs argue that Dr. Bales opines that mesh contraction does not "lead to complications of clinical consequence" and "shrinkage is of no clinical importance." Mem. Supp. Mot. re: Dr. Bales 9–10. Dr. Bales, however, actually opines that "[t]here is no medical literature conclusively establishing that mesh contracts with vaginal use to clinically significant degrees." Bales Report 8. Dr. Bales cites to published studies regarding his opinion, and he relies on his own clinical experience in arriving at his opinions. Further, Dr. Bales explained why he chose not to rely on certain contrary studies. To the extent that the plaintiffs believe that Dr. Bales failed to consider contrary scientific studies, they may cross-examine Dr. Bales on those points. The plaintiffs' Motion regarding Dr. Bales's opinions on complications associated with mesh contracture is **DENIED**.

### c. Selective Review

The plaintiffs ask the court to exclude as unreliable Dr. Bales's opinions insofar as any opinions are based on his allegedly selective review of medical literature. The plaintiffs do not, however, indicate which opinions are founded on his allegedly selective review of medical literature. I will not parse through an expert's report to determine whether a party's broad claim of unreliability has any merit; it is the party's obligation to support its motion. Accordingly, the plaintiffs' Motion is **DENIED** on this point.

## V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard*, 81 F.3d at 920 (“[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value.”). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors “to erroneously conclude that regulatory compliance proved safety.” *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement

actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon's compliance with design control and risk management standards. Some of this testimony involves the FDA's quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed

for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

*First*, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) (“[O]pinion testimony that states a legal standard or draws a legal conclusion

by applying law to the facts is generally inadmissible.”); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) (“Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.”). Additionally, an expert may not offer expert testimony using “legal terms of art,” such as “defective,” “unreasonably dangerous,” or “proximate cause.” *See Perez v. Townsend Eng’g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

*Second*, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

*Third*, many of the motions also ask the court to require an expert to offer testimony consistent with that expert’s deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

*Fourth*, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed

may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

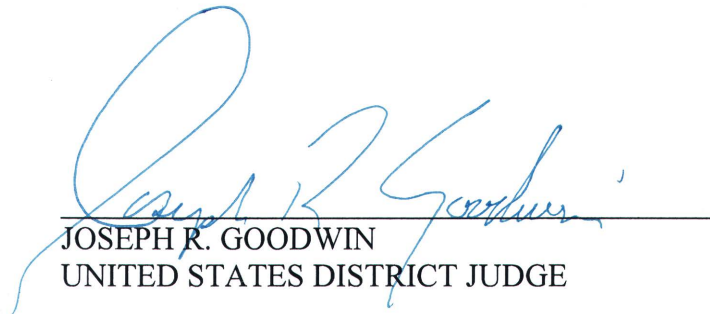
*Finally*, in some of the *Daubert* motions, without identifying the specific expert testimony to be exclude, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

## **VI. Conclusion**

The court **DENIES in part, GRANTS in part, and RESERVES in part** the Motion to Exclude the General Opinion Testimony of Dr. Gregory T. Bales, M.D. [ECF No. 2054].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: August 25, 2016



JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE

**EXHIBIT A - BALES**

<b>CASE STYLE</b>	<b>CASE NUMBER</b>
Joy Essman v. Ethicon, Inc., et al.	Case No. 2:12-cv-00277
Christine Wiltgen v. Ethicon, Inc., et al.	Case No. 2:12-cv-01216
Shirley Walker v. Ethicon, Inc., et al.	Case No. 2:12-cv-00873
Julie Wroble v. Ethicon, Inc., et al.	Case No. 2:12-cv-00883
Nancy Jo Williams v. Ethicon, Inc., et al.	Case No. 2:12-cv-00511

## Exhibit C

### Index of Relevant Pleadings related to Gregory T. Bales, M.D.

Judge Goodwin instituted a series of Waves in MDL 2327 wherein he identified hundreds of cases per Wave subject to discovery and motion practice deadlines. As part of the Wave process, Judge Goodwin required parties to file one general causation *Daubert* motion per expert per Wave in the main MDL, rather than in each individual Wave case. Parties were required to identify the cases in each Wave to which a particular *Daubert* motion applied. The court has identified below, the relevant *Daubert* pleadings filed in each Wave (and in many cases ultimately adopted in subsequent Waves) for the court receiving this case on remand or transfer.

Wave 1	Date	WVSD ECF No.
Motion	4/21/16	2054
Memorandum	4/21/16	2057
Response	5/9/16	2177
Reply	5/16/16	2243
Mem Op & Ord	8/25/16	2665

Wave 2	Date	WVSD ECF No	Comment
Motion	7/21/16	2392	Adopts ECF No. 2054
Memorandum	7/21/16	2392	Adopts ECF No. 2057
Response	8/5/16	2489	Adopts ECF No. 2177
Reply	8/18/16	2592	Adopts ECF No. 2243
Mem Op & Ord	12/16/16	3275	Adopts ECF No. 2665

Wave 3	Date	WVSD ECF No	Comment
Motion	9/19/16	2796	Adopts ECF No. 2054
Memorandum	9/19/16	2796	Adopts ECF No. 2057
Response	10/11/16	2914	Does not adopt
Reply	10/21/16	3038	Adopts ECF No. 2243